

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re Bair Hugger Forced Air Warming Devices
Products Liability Litigation

MDL No. 15-2666 (JNE/DTS)

This Document Relates to:
Trombley v. 3M Co., No. 16-cv-4159

**DEFENDANT 3M COMPANY’S MEMORANDUM IN OPPOSITION
TO PLAINTIFF’S MOTION TO STRIKE PORTIONS OF 3M’S
CASE-SPECIFIC EXPERT REPORTS**

Plaintiff’s motion to strike portions of 3M’s case-specific expert reports in *Trombley* should be denied. Each of the reports calls out key facts from Ms. Trombley’s medical history or identifies features of the operating room where her surgery took place, and then analyzes pertinent medical and scientific literature to help the jury understand why the Bair Hugger system did not cause Ms. Trombley’s surgical site infection. To the extent the reports address generally applicable issues from earlier reports, they do so in service of their *specific* analysis of Ms. Trombley’s case, and in rebutting the case-specific opinions of Plaintiffs’ expert, Dr. Jarvis. None of that discussion gives rise to any previously undisclosed “general causation” opinions, which Plaintiffs have already examined in multiple depositions and at trial. They apply to those general principles *to Ms. Trombley’s case*, just as a case-specific report is supposed to do.

This is in sharp contrast to the two expert reports the Court excluded last September. Those reports did not pretend to be case-specific: one was a supplemental report that added

major new opinions on “safer alternatives” to the Bair Hugger system, and the other was a sur-rebuttal that the Court had previously disallowed. Although the reports were served in the *Axline* case, neither one even attempted to apply the author’s general opinions to the specific facts surrounding Ms. Axline’s surgery. The Court properly excluded them in its Order of September 19, 2018 (MDL Doc. 1522).

Plaintiffs’ present motion is based on an overreading of that Order. Plaintiffs claim the Order imposed “an artificial governor limiting the universe of opinions and potentially other evidence that can be offered,” which they believe bars experts from citing literature on previously disclosed topics, or even *discussing* those topics, in formulating their specific causation opinions. But the Order said no such thing. There was no broad-brush prohibition on exploring general scientific issues in the context of individual plaintiffs’ cases. Nor could there be: a valid specific causation analysis *requires* an expert first to “rule in” general causes, then filter them through the facts of the Plaintiffs’ case. *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001). 3M’s case-specific *Trombley* reports follow exactly this method in rebutting Plaintiffs’ experts’ case-specific opinions. Plaintiffs clearly do not really believe their own specious interpretation of the Court’s Order, because their own case-specific Dr. Jarvis addresses his general causation opinions and applies them to Ms. Trombley’s case.

If Plaintiff’s motion is successful, 3M’s experts will be substantially foreclosed from explaining why they conclude that Plaintiff cannot prove causation in *this* case. They will not be able to discuss the risk factors in Plaintiff’s medical history that Plaintiff’s expert, Dr. Jarvis, could not validly rule out. They will not be able to discuss the impact

of, for example, operating room traffic on airflow in Trombley's operating room. And they would not be allowed to discuss the literature they actually relied upon in forming their opinions. In short, Defendants' experts would not be able to provide the jury the full benefit of their expertise and case-specific analysis.

At bottom, Plaintiffs have not shown that 3M's *Trombley*-specific experts' reports are not case-specific reports or that any general opinions fall outside the core opinions disclosed in their previous reports and trial testimony. Of the five experts whose reports are challenged, four have given multiple days of deposition testimony, and each will presumably undergo hours more of questioning on their case-specific opinions (if Plaintiffs chose to take those depositions). Thus, Plaintiffs also cannot show *any* prejudice, much less the degree of prejudice necessary to justify the extreme remedy of excluding experts and barring their reports. Plaintiffs' motion should be denied.

BACKGROUND

Following Pretrial Order No. 17, on March 31, 2017, Plaintiffs disclosed initial MDL reports from experts in orthopedic surgery (Dr. Michael Stonnington), infectious disease (Dr. William Jarvis), epidemiology (Dr. Jonathan Samet), hospital ventilation (Daniel Koenigshofer and Michael Buck), biomedical engineering (Dr. Yadin David), and fluid dynamics (Dr. Said Elghobashi). On June 2, 2017, 3M served rebuttal reports from experts in the same disciplines as Plaintiffs', while also bringing new expertise—including nursing, anesthesiology, microbiology, and schlieren imaging—to bear on Plaintiffs' theories. 3M's rebuttal reports were not limited to the four corners of Plaintiffs' reports,

but generally engaged the basic question that Plaintiffs posed: does the Bair Hugger system cause periprosthetic joint infections?

Shortly after the October 2017 MDL *Daubert* hearings, the parties served case-specific expert reports in the *Gareis* bellwether case (November 27, 2017 for Plaintiffs, and December 18, 2017 for Defendants). After receiving 3M's experts' case-specific reports, Plaintiffs did not raise any complaints of improper rebuttal or inappropriate supplementation. Likewise, 3M did not critique the scope (as opposed to the merits) of Plaintiffs' case-specific expert reports. *Gareis* was tried in May 2018. During the trial, Plaintiffs' biomedical engineering expert, Dr. David, testified that the TableGard—a device which he had never seen, and about which he knew nothing beyond the contents of a marketing brochure—was a safer alternative to the Bair Hugger system.

Axline was the first case after the *Gareis* verdict in which the parties served expert reports. On August 13, 2018, Plaintiffs served a *supplemental* report—not a case-specific report—from Dr. David, in which he introduced seven new “safer alternatives” that were never disclosed in his initial MDL report. The report contained no discussion of the facts of Ms. Axline's case. Plaintiffs also submitted a report from a new CFD expert, Dr. Nathan Bushnell. Like David's report, Bushnell's report was not case-specific; its sole aim was to critique the work of 3M's CFD expert, Dr. John Abraham. The only case-specific report that Plaintiffs served in *Axline* was that of their infectious disease expert, Dr. Jarvis, who opined that the Bair Hugger system caused Ms. Axline's infection.

3M moved to bar the David and Bushnell reports, and the Court granted the motion. 9/19/2018 Order, MDL Doc. 1522. The Court recognized that Dr. Bushnell's report was

an improper sur-rebuttal disallowed by its prior Orders. *Id.* at 3-4. As for Dr. David, the Court found that the newly disclosed “alternatives” in his supplemental report were all known or knowable at the time of his initial MDL report, or at the latest by his August 1, 2017 MDL deposition. *Id.* at 3. By the time David submitted his supplemental report, general MDL discovery had already been closed for more than a year, and the *Axline* trial was only 4 months away. *See* Pretrial Order No. 17, ¶10 (general MDL discovery closed March 20, 2017) and Pretrial Order No. 26, ¶6 (reaffirming trial readiness date of December 3, 2018 for *Axline* as the parties’ remaining Joint Nominee). Recognizing 3M’s inability to obtain adequate discovery of David’s new alternatives under “the shadow of the looming *Axline* bellwether trial,” the Court barred his supplemental report. 9/19/2018 Order, Doc. 1522 at 5.

3M did *not* move to bar any portions of Dr. Jarvis’s case-specific report in *Axline*, even though it also revisited general causation issues and cited new sources on general topics. *See, e.g.,* Jarvis *Axline* Case-Specific Report (Ex. 1) at 13-14 (discussion of Elghobashi CFD and McGovern study) and 16 (citing new study by Scholten et al. on incidence of mild hypothermia after total knee or hip arthroplasty). 3M took Dr. Jarvis’s discussion of general cause and related literature to fall fairly within the bounds of a specific causation analysis, because they were applied specifically to *Axline*.

The parties recently served case-specific expert reports in *Trombley*. Plaintiffs submitted reports from Dr. Jarvis and a new expert, Dr. Eric Brown, a nephrologist who opines that Ms. Trombley’s kidneys were damaged by antibiotics used to treat her

infection.¹ Dr. Jarvis’s case-specific opinions rely on the same sources—McGovern, Stocks, Darouiche, and the Elghobashi CFD—that he relied on in his MDL, *Gareis*, and *Axline* reports. In addition, Dr. Jarvis ventures opinions in areas outside his core discipline of infectious diseases. For example:

- **Orthopedic Surgery.** “I am unaware of any reports of contaminated surgical tools or supplies, nor any deviations from standard surgical practice or infection control procedures [during Ms. Trombley’s surgery]. Based on my review of available records, the medical care comported with all accepted standards of medical and surgical practice.” Jarvis *Trombley* Report (Ex. 2) at 5-6.
- **Anesthesiology.** “Based on the testimony of . . . [Anesthesiologist] Dr. Abdul-Aziz, and the [Certified Registered Nurse Anesthetist] Peterson, I am even more confident that there are no other likely, potential causes of bacteria reaching the sterile field during Mrs. Trombley’s surgery.” *Id.* at 10.
- **HVAC.** “I reviewed the HVAC system operating manual, and it shows unequivocally that the air exchange rates were well in excess of what ASHRAE standards prescribe (20 exchanges/hour) . . . Without some kind of affirmative evidence to suggest the system did not perform as designed, there is no plausible basis to suggest the HVAC system contributed to Mrs. Trombley’s infection.” *Id.*
- **CFD.** “I find persuasive the expert CFD report of Dr. Said Elghobashi regarding the Bair Hugger 750, along with his supplemental report regarding the impact of the Bair Hugger 505, on the OR unidirectional airflow. According to Dr. Elghobashi’s study, the Bair Hugger causes significant disruption of OR airflow, leading to increased number of particles and skin squames over and in the sterile field.” *Id.* at 8.

¹ Dr. Brown’s report is not really about specific *causation*—he expresses no view on whether the Bair Hugger system caused Ms. Trombley’s infection.

3M then served case-specific reports to rebut the opinions of Drs. Brown and Jarvis regarding the specific cause of Ms. Trombley's surgical infection and sequelae. These included reports from:

- **Dr. Michael Mont (orthopedic surgery).** Dr. Mont reviewed Ms. Trombley's extensive medical history and identified important risk factors for infection that Dr. Jarvis either discounted or ignored. He also discussed potential sources of infective bacteria commonly found in operating rooms that could not be ruled out in Ms. Trombley's case. Dr. Mont's review of Ms. Trombley's risk factors and sources of bacterial contamination are backed by cited literature.

- **Dr. Richard Dutton (anesthesiology).** Dr. Dutton, an anesthesiologist who has used the Bair Hugger system in thousands of surgeries over the past 20 years, also reviewed Ms. Trombley's medical history and identified her as being at higher risk for surgical infection. To the extent he addresses general points, it is to rebut statements made by Dr. Jarvis in his case-specific report.

- **Michael Keen (HVAC).** Mr. Keen visited operating room #3 at Bay Park Hospital in Oregon, Ohio, where Ms. Trombley's surgery took place. He noted airflow obstructions and idiosyncratic features of the HVAC system that could easily overwhelm any turbulence occasioned by the comparatively mild flow of air from the Bair Hugger blanket. Moreover, he opines that those features themselves could have increased the risk of airborne bacteria-carrying particles reaching the sterile field during Ms. Trombley's surgery.

- **Dr. John Abraham (CFD).** Dr. Abraham rebuts Dr. Jarvis's reliance on the Elghobashi/Apte CFD for his specific causation conclusion. He also discusses research on OR traffic, door openings and closings, and airflow obstructions—all of which must have occurred during Ms. Trombley's surgery—and discusses their effects on OR airflow. Finally, he examines photographs taken during the site visit to OR #3 to opine on their likely effects on airflow during the surgery, and to observe that the Elghobashi/Apte CFD model leaves all of those important details out.

- **Dr. Jonathan Borak (epidemiology).** Like Dr. Mont, Dr. Borak identifies Ms. Trombley's many risk factors for surgical infection and discusses the medical literature on each. He also rebuts Dr. Jarvis's reliance on the McGovern study for his specific causation conclusion, citing recent literature casting further doubt on the validity and credibility of that paper.

- **Dr. Randy Luciano (nephrology).** Dr. Luciano rebuts Plaintiffs' case-specific nephrologist Dr. Brown regarding the extent to which Ms. Trombley's antibiotic treatment caused or contributed her current kidney condition.

Plaintiffs now move to exclude five of Defendants' six case-specific reports on two grounds: first, because they revisit general issues and discuss previously uncited articles in their specific causation analysis; and second, because Defendants' experts come from fields other than Dr. Jarvis's. Neither is a valid basis for excluding or limiting Defendants' *Trombley*-specific expert reports.

ARGUMENT

I. THE DEFENSE EXPERTS' *TROMBLEY* REPORTS ARE PROPER CASE-SPECIFIC REBUTTAL REPORTS.

The reports submitted by 3M's experts in *Trombley* address case-specific facts, and will help the jury understand why the Bair Hugger system did not cause Ms. Trombley's surgical infection. "It is the proper role of rebuttal experts to critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiff's experts' reports." *Aviva Sports, Inc. v. Fingerhut Direct Marketing, Inc.*, 829 F. Supp.2d 802, 835 (D. Minn. 2011). This is precisely what 3M's experts have done in their case-specific reports here. They address risk factors and alternative causes that Plaintiff's expert, Dr. Jarvis, either downplays or disregards entirely. Plaintiffs' brief does not identify a single statement that is not either a rebuttal to Dr. Jarvis or to Plaintiffs' allegation that the Bair Hugger system caused Ms. Trombley's infection.

Plaintiffs next argue that 3M's orthopedic surgeon, anesthesiologist, HVAC engineer, and fluid dynamicist must be excluded as "improper rebuttal" because Dr. Jarvis lacks any of these qualifications himself. As noted, however, Dr. Jarvis offered opinions in each of those areas, notwithstanding his lack of expertise. Simply because a rebuttal expert is not in the same field as the other side's initial expert does not make the rebuttal expert's opinion improper. Fundamentally, the determination of whether an expert is properly considered "initial" or "rebuttal" does not turn on the scope of her expertise, but rather on the burden of proof. *Cf.* Fed. R. Civ. P. 26(a)(2) advisory committee's note ("[I]n most cases the party with the burden of proof on an issue should disclose its expert testimony on

that issue before other parties are required to make their disclosures with respect to that issue.”). “Rebuttal” expert reports are simply the reports of the party (in this case, 3M) that does not have the burden of proof. This is exactly what the Court has explained in previous hearings on this issue. *See, e.g.*, 9/8/16 MDL Status Conf. Tr. (Ex. 3) at 18 (“[B]y “initial expert,” I understand that to be any expert witness that a party is going to call to testify about an issue as to which that party has the burden of proof. So under these circumstances, nearly all of the initial experts presumably would be on the plaintiff’s side.”).

Plaintiffs’ motion does not claim that 3M’s case-specific reports violate Rule 26 or Pretrial Order No. 27. To the extent Plaintiffs are claiming some sort of prejudice from the fact that 3M’s case-specific experts were designated as rebuttal experts, that would be easily remedied by proceeding with their depositions.² *See Soo Line R. Co. v. Werner Enters.*, 8 F. Supp. 3d 1130, 1138 (D. Minn. 2014) (refusing to exclude rebuttal expert reports due to lack of prejudice, since moving party “had a sufficient opportunity to depose” the experts following their identification).

II. 3M’S CASE-SPECIFIC EXPERT REPORTS FULLY COMPLY WITH THE COURT’S PRIOR ORDERS.

Pretrial Order No. 27 anticipates that the parties’ experts will address general causation issues in the context of individual bellwether cases. *See* PTO 27 ¶4.d. (“If an expert has testified about general causation, a party deposing that expert witness may not explore general causation *unless as incidental to a specific causation inquiry*”) (emphasis

² To date, Plaintiffs have only agreed to depose two of 3M’s experts – Dr. Mont on March 22 and Dr. Dutton on March 21. Dates have been offered but not accepted for Drs. Luciano, Borak, Abraham, and Mr. Keen.

added). The Court's September 9, 2018 Order excluding David's supplement and Bushnell's sur-rebuttal did not declare that experts may not apply their general opinions to specific cases; it merely affirmed the bar on sur-rebuttals and excluded seven belatedly disclosed "safer alternative designs." While Plaintiffs maintain (notwithstanding the report of their own expert, Dr. Jarvis) that experts may never talk about general issues as applied to specific cases, there is no Court Order that says this.

Nor did 3M request more than this relief. 3M did not seek to cast the MDL "general cause" reports forever in stone—to the contrary, in their brief 3M pointed out the inevitability "in a lengthy, complex litigation" that an expert would "discover and wish to disclose additional studies that support her or his previously disclosed opinions." MDL Doc. 1436 at 1.

Plaintiffs' contention that 3M's experts cannot discuss general issues in their *Trombley* reports, or in any individual case, makes no sense. Before an expert can address specific causation – *i.e.*, whether the Bair Hugger system caused Ms. Trombley's infection – the expert must first consider generally accepted causes and sources of infections. *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001) ("In performing a differential diagnosis, a physician begins by 'ruling in' all scientifically plausible causes of the plaintiff's injury."). Different causes and sources will come into play, depending on the Plaintiff's risk factors and exposures. But there are no sources or causes of infection that are "unique," in the sense that they have not been studied and found to occur with other patients under similar circumstances. It would be impossible for the parties' experts to

explain their case-specific opinions to the jury without discussing research on generally known causes and sources of infection that bear on the case at hand.

Dr. Jarvis's *Trombley* report exemplifies this approach. The McGovern study is the mainmast of his specific causation opinion, and Elghobashi's CFD is its main sail:

The McGovern study and/or Dr. Elghobashi's CFD model paired with the Stocks and Darouiche studies each independently confirm that the Bair Hugger is the most likely cause of Ms. Axline's PJI.

While 3M disagrees with Dr. Jarvis's specific causation opinion, and disputes the validity of both his methodology and his support, 3M does not take issue with the basic approach of citing generally applicable literature when conducting a case-specific analysis.³

Unlike Dr. David's seven belated "alternatives," Plaintiffs' motion does not call out any wholly new, non-case-specific opinions in the defense experts' *Trombley* reports. At most, Plaintiffs' highlights of those reports identify new *support* for previously disclosed opinions. But here again, nothing in the Court's prior Orders prohibits an expert from expanding upon earlier statements of general opinions in the context of a specific case. Indeed, this Court has previously concluded that experts may elaborate on opinions expressed in earlier reports, so long as they stay within the bounds of their core opinions. *Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, 829 F. Supp.2d 802, 821 (D. Minn. 2011)

³ Given the centrality of McGovern and Elghobashi to Jarvis's opinions about Ms. Trombley's case, Plaintiffs could not reasonably expect to avoid a critique of those studies in 3M's experts' case-specific reports. Yet every mention of the McGovern study is highlighted in the exhibits to Plaintiffs' motion. If the same criteria were applied to Dr. Jarvis's *Trombley* report, it too would be heavily highlighted. *See* Ex. 4 (Jarvis *Trombley* report highlighted by 3M, applying Plaintiffs' criteria).

(“The Court does not find that these declarations contain ‘new opinions’—they contain no new material information and present no opinions that were not provided during discovery. The experts’ declarations merely clarify their reports”). Other Courts have similarly allowed experts to provide additional support for previously disclosed opinions. *See In re Accutane Prods. Liab. Litig.*, 2007 WL 201091, at *1 (M.D. Fla. Jan. 24, 2007) (denying motion to strike supplemental report discussing “additional literature review” and “a degree of new or additional rationale in support of the expert’s conclusions,” since “the core opinions remain the same”); *see also Faulkner v. Arista Records LLC*, 46 F. Supp. 3d 365, 378 (S.D.N.Y. 2014) (allowing supplemental report after close of discovery because “[a]ll of these topics were covered in varying levels of detail in [the expert’s] initial expert report,” and because the expert had “been deposed on these topics so the risk of prejudice is low”). 3M’s experts’ *Trombley* reports merely supply additional sources relating to opinions that Plaintiffs have long known and on which the experts have already been thoroughly examined. They are unlike the excluded supplemental report of Dr. David, which went far beyond his original, core opinions in proposing seven additional alternative designs.

A. Dr. Abraham.

Plaintiffs highlight Dr. Abraham’s discussion of literature on the position and movement of flow obstructions in his *Trombley* report; the number, position, and movement of surgical staff; and door openings and traffic in and out of the operating room in *Trombley*’s surgery. Yes, he discussed these issues generally in his general causation rebuttal report, but here he applies them in the context of *Trombley*’s case. Plaintiffs

cannot show that there were no airflow obstructions from equipment, no movement of surgical staff, and no traffic in or out of the operating room during Ms. Trombley's procedure. Thus, all of those topics are relevant areas for Dr. Abraham to discuss in his case-specific analysis.

B. Dr. Borak.

Plaintiffs highlight Dr. Borak's citations to studies on risk factors for periprosthetic joint infection, including obesity, diabetes (both "well controlled" and "uncontrolled"), anemia, chronic kidney disease, and opioid use. Plaintiffs did *not* highlight, however, Dr. Borak's preceding recitation of Ms. Trombley's medical history, in which he identifies each of those conditions as risk factors *in her case*. See *Borak Trombley Report*, Pl. Ex. 2, at 2-7. Plaintiffs also highlight Dr. Borak's discussion of the Jeans study and other articles co-authored by Augustine ally Dr. Mike Reed, but Plaintiffs recently examined Dr. Borak on exactly those articles for two hours. Moreover, as explained in 3M's pending motion for reconsideration, the Jeans study casts extreme doubt on the validity and credibility of the McGovern study, which is the centerpiece of Dr. Jarvis's specific causation opinion. As such it is well within the scope of a case-specific rebuttal report.

C. Dr. Dutton.

Dr. Dutton's opinions are also case-specific; all of his opinions are tied to his analysis of Ms. Trombley's case. Dr. Dutton was disclosed in *Trombley* because Dr. Alexander Hannenberg, the anesthesiologist 3M called in the *Gareis* trial, was unavailable for the *Trombley* trial. To the extent that Dr. Dutton expresses opinions that apply beyond Ms. Trombley's case, they fall squarely within the parameters of Dr. Hannenberg's MDL

report and *Gareis* trial testimony. Plaintiffs seem to be saying that Dr. Dutton's *Trombley* report must be word-for-word *identical* to Dr. Hannenberg's to avoid being excluded, but they cite no support for that argument.

D. Mr. Keen.

Plaintiffs have not highlighted any statements in Mr. Keen's *Trombley* report. To the extent Plaintiffs argue that Mr. Keen should be excluded because Dr. Jarvis is not an HVAC expert, that argument fails for the reasons already discussed.

E. Dr. Mont.

Plaintiffs highlight Dr. Mont's statements regarding risk factors for periprosthetic joint infection including transient bacteremia from oral sources, malnutrition, renal disease, corticosteroid usage, type 2 diabetes, obesity, ASA grade 3, opioid/narcotic usage, pre-operative anemia, Vitamin D deficiency, hypertension, hypercholesterolemia, and recurrent urinary tract infections. As with Dr. Borak, Dr. Mont identified each of these risk factors in Ms. Trombley's medical history. *See* Mont *Trombley* Report, Pl. Ex. 5, at 7-24. His discussion of the literature regarding each risk factor is therefore an appropriate part of his case-specific analysis. Plaintiffs also highlight Dr. Mont's discussion of the importance of maintaining patient body temperature and sources of bacteria in the operating room, but he has already testified extensively on both topics in depositions and at the *Gareis* trial. There is no basis for prohibiting him from testifying about those topics, both of which are highly relevant to Ms. Trombley's case.

CONCLUSION

3M's case-specific expert reports in the *Trombley* case fall well within the bounds of case-specific analysis, proper rebuttal, and the experts' previously disclosed opinions. The reports also fully comply with the Court's previous Orders. Plaintiffs cannot meet their burden to demonstrate otherwise. Moreover, Plaintiffs have not shown any prejudice that would justify excluding the reports or any portions of them. Plaintiffs' motion to exclude 3M's case-specific expert reports should therefore be denied.

DATED: March 5, 2019

Respectfully submitted,

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